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PATENT

Attorney Docket No. 03495.0362-09000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

HERVE LE MOUELLIC et al.

Application No.: 10/770,418

Filed: February 4, 2004

For: PROCEDURE FOR SPECIFIC
REPLACEMENT OF A COPY OF A GENE
PRESENT IN THE RECIPIENT GENOME
BY THE INTEGRATION OF A GENE
DIFFERENT FROM THAT WHERE THE
INTEGRATION IS MADE

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) Group Art Unit: 1632
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) Examiner: Wu-Cheng Winston Shen
)
) Confirmation No.: 1932
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed October 3, 2006, the Examiner required an election under 35 U.S.C. § 121 between the following six groups of claims:

- I. Claims 24-28, 38-44, and 78, drawn to a DNA gene inactivation construct for homologous recombination in the genome of a mammalian cell, classified in class 536, subclass 23.1.
- II. Claims 29-30 and 52-67, drawn to a DNA construct, encoding no fusion protein before homologous recombination, classified in class 536, subclass 23.1.
- III. Claims 31-37, drawn to a DNA construct comprising DNA encoding a transcriptionally and translationally impaired positive selectable marker gene, classified in class 536, subclass 23.1.
- IV. Claims 45-51, drawn to a DNA gene inactivation construct, encoding no fusion protein either before or after homologous recombination, classified in class 536, subclass 23.1.

- V. Claims 68-77, drawn to a DNA construct, encoding two distinct gene products, comprising a first DNA sequence and a second DNA sequence, classified in class 536, subclass 23.1.
- VI. Claims 79-101, drawn to a method for modifying a target DNA sequence in a mouse embryonic stem cell, classified in class 800, subclass 21.

The Examiner further required that additional elections be made if one of Groups I-V is elected. As an initial matter, Applicants note that it is not at all clear which subject matter the Examiner would like for them to choose from in making this election. Nonetheless, based on the limited explanation in the Restriction Requirement, Applicants are making a bona fide attempt to fully respond.

Election and Traversal

In response, Applicants provisionally elect to prosecute Group V, Claims 68-77 drawn to a DNA construct, encoding two distinct gene products, comprising a first DNA sequence and a second DNA sequence, classified in class 536, subclass 23.1, **with traverse**. Applicants further elect to prosecute the specific combination of a receptor. Such an embodiment is recited in claim 71 and is clearly also encompassed by claim 68.

Applicants' traversal is on the ground that the Examiner has not demonstrated that restriction is proper. "There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; **and** (B) There must be a serious burden on the examiner if restriction is required." M.P.E.P. § 803 (emphasis added). Thus, "If the search and

examination of all the claims in an application can be made **without serious burden**, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions.” M.P.E.P. § 803 (emphasis added). Applicants respectfully submit that the Examiner has not demonstrated that examination of the full scope of the claims represents a serious burden and that, therefore, the restriction requirement is improper and should be withdrawn.

Regarding the second requirement, that Applicants elect a specific combination, Applicants submit that the requirement is improper and should be withdrawn. Elected claim 68 is generic with respect to the combinations that the Examiner would have Applicants choose from. Yet, the Examiner indicated that this is a restriction requirement and not an election of species requirement. In making this restriction requirement, then, the Examiner would have Applicants choose a single species of the invention for examination. Under such a scenario, no matter how many divisional applications Applicants might file, no combination of species claims prosecuted in those applications can fully encompass the subject matter of generic claim 68. Thus, this requirement is tantamount to a refusal by the Office to examine claim 68, which is what Applicants regard as their invention. Accordingly, in making this requirement the Office is improperly refusing to examine Applicants' invention. Applicants submit that this requirement is therefore improper and respectfully request that the Examiner reconsider and withdraw it.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: November 3, 2006

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